INSTRUCTIONS FOR USE

Please read before use

IMPORTANT PRODUCT INFORMATION

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Category: Bone Graft Substitute

Product Description

Actifuse Flow contains Actifuse, an osteoinductive, phase-pure, porous, silicate substituted calcium phosphate bone graft substitute. Actifuse contains 0.8% silicon by weight, similar to the bone mineral of natural bone. Calcium phosphate bone graft substitutes have been the topic of extensive clinical studies for several decades. Actifuse Flow is in safe and has excellent biocompatibility. The interconnected macro- and micro-porous structure and enhanced surface chemistry of Actifuse Flow encourages the rapid formation of host bone and the growth of capillary blood vessels throughout the network of interconnected pores. Actifuse is osteoinductive based upon in vitro studies that show that cellular responses, such as metabolic activity and proliferation, are accelerated when compared to an identical material that did not contain 0.8% silicon by weight. After it is implanted, Actifuse undergoes physiologically-mediated resorption and is replaced by natural bone. Actifuse has a resorption time that lies between the least soluble pure hydroxyapatite and the most soluble form of tricalcium phosphate.

Actifuse Flow is supplied in a sterile polypropylene syringe and contains Actifuse granules, with 80% (±2.5%) porosity and a granule size range of 0.09 – 0.5 mm, suspended in an aqueous gel carrier. Actifuse has a resorption time that lies between the least soluble pure Hydroxyapatite and the most soluble form of tricalcium phosphate.

Actifuse is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse Flow can be injected into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in postmortem spinal fusion procedures with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Possible Complications

Successful results may not be achieved in every surgical case. Reoperation to remove or replace an implant may be required due to specific medical conditions or device failure. Possible adverse effects may include but are not limited to:

- Osteoinductive and osteostimulatory properties of Actifuse Flow allow for modeling and remodeling of the bone and the implant to ensure proper bone regeneration. The effect of Actifuse Flow on patients with the following conditions is unknown:
  - insufficient bone mass
  - bone deformity at the site
  - delayed or non-union / lack of bone integration
  - transient hypercalcemia

Implant. Secure the surgical site after implanting to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. Fully fill the bony defect ensuring maximal contact between Actifuse Flow and the host bone. Do not overtight or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, or may lead to fist embolization or embolization of the device into the bloodstream.

Dosage is for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use. Instructions for use:

Step 1. Open both the outer (non-sterile) pouch and inner (sterile) packaging.

Step 2. Remove syringe cap gently depress the syringe plunger using a palm grip as shown in pictures 1 and 2 below to expel Actifuse Flow from the syringe. Dispense Actifuse Flow into the bony defect site and make sure maximal contact between Actifuse Flow and the host bone. Do not use too much force when placing applicator tip on defect site. This may result in bending of the applicator tip leading to restriction of Actifuse Flow through the applicator tip. Actifuse Flow is designed to be used alone.

Step 3. Implant. Secure the surgical site after implanting to prevent micro-motion and implant migration. When excess fluid is present at the surgical field, the surgeon may use cautery, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new package of Actifuse Flow.

Storage, Shelf Life and Disposal

Product should be stored between 10 – 70% Relative Humidity and 5 – 32°C (40 – 90°F).

The expiration date is printed on the label. DO NOT USE ACTIFUSE FLOW AFTER THE EXPIRATION DATE. Actifuse Flow is environmentally friendly. No special disposal is necessary.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital.

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of Actifuse Flow, and for the choice of post-operative follow-up procedures rests entirely with the physician.

Manufactured by: AptaTech Ltd. 370 Centennial Avenue, Centennial Park, Elthorne, Hertfordshire, WD6 3JZ, UK

Distributed by: Baxter Healthcare Corporation, Deerfield, IL 60015 USA ( Toll Free ) 1-888-229-0001

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